



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Greenway et al

Atty Doc. #: 099042-00

Serial No.: 10/713,518

Examiner: David B. Jones

Filed: November 14, 2003

Group: 3725

For: Waist Chain

**DECLARATION OF KEN FUJIOKA, M.D.**

I, Ken Fujioka, declare as follows:

My educational background and professional qualifications are set forth on the attached Exhibit A. In summary, I have conducted research within the field of obesity since 1988 when I did my fellowship with USC Medical School. I presently serve as the director of the Nutrition and Metabolic Research Center at Scripps Clinic, as well as the Center for Weight Management. Approximately half of my day is spent doing research in the field of obesity and the other half is seeing patients for obesity treatment.

I have reviewed the above referenced patent application as well as the literature cited on the attached Exhibit B regarding studying "abdominal belting" and the use of a nylon cords or monofilament nylon lines fastened around the waist to maintain or lose weight. At the Scripps Clinic Center for Weight Management we see an average of 150 to 200 patients a week for obesity and take a detailed history of methods used to lose or maintain weight loss. During the past 10 years of my professional experience, I have neither personally seen nor heard of any patient using abdominal belting as a means for maintaining or losing weight, and to my knowledge, using a restrictive method such as abdominal belting is not presently used as a means for maintaining or losing weight anywhere nor has it been used for many years. Despite the

disuse of abdominal belting, there continues to be a great need for diverse methods to control obesity.

The literature cited in Exhibit B indicates that abdominal belting, at the time the studies were conducted and when properly worn by patients, had positive results. Despite those positive results, abdominal belting fell into disuse. I believe this disuse was a direct result of inherent properties of then-used nylon cords and nylon monofilament that resulted in unmanageable discomfort to the patients as well as posed potential sanitary risks. For example nylon cords and nylon monofilaments likely cut into the skin of patients causing severe discomfort and held bacteria (as a result of its porosity) that potentially resulted in skin infections.

I believe the beaded waist chain of the above referenced application possesses major advantages over the abdominal belting materials (e.g. nylon cords and nylon monofilaments) disclosed by the literature cited in Exhibit B. One of the most common problems in the obese population is fungal skin infections. This particular type of rash is usually found on the trunk of patients under the breasts in women, in the groin area, and under the pannus (belly) of the protruding abdomen. The location of the human body intended for abdominal belting is an area of high risk for a fungal rash. Non-porous material, such as stainless steel, will have a huge advantage over a nylon cord due to its inert nature. Using a material that is bacterial and fungal resistant is essential to any device intended to be worn in contact with the skin for the length of time required for abdominal belting.

Weight maintenance in the obese population is very difficult to achieve after weight loss. Abdominal belting acts as a physical stimulus providing immediate feedback to the user that he or she has lost or gained weight. I believe the ease of removing the nylon cords and nylon monofilaments contributed to the disuse of prior abdominal belting methods. When discomfort

overcame the willpower of the patient, the patient could simply cut the nylon cord or monofilament with a pair of scissors. I believe the beaded chain of the above referenced application will make the waist chain much more difficult to remove. As mentioned, impulsivity can be a real problem in obesity, and having the patient taking the extra time to obtain a pair of wire cutters will help keep the string of beads on longer. The data appears to be quite clear that once the belt comes off the weight can return.

I believe the method of using the waist chain as disclosed in the above referenced application has great potential to help in controlling obesity. Had beaded waist chains been used in lieu of nylon cords or monofilaments, it is my opinion that abdominal belting may not have fallen into disuse. I see this method as very unique. The use of non-porous beads has an excellent advantage over other materials in terms of skin infections and comfort. Further, the beads have the potential to stay on much longer which is key in keeping the weight off.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: Sept 7, 2005

  
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Ken Fujioka, M.D.

Director of Nutrition and Metabolic Research  
Scripps Clinic,

## **EXHIBIT A**

### **KEN FUJIOKA, M.D. Curriculum Vitae**

#### **EDUCATION**

San Diego State University, B.A., Microbiology, honors degree, 1976  
University of Southern California, graduate work in physiology  
University of Hawaii, graduate work in biochemistry  
University of Hawaii School of Medicine, M.D., 1983

#### **POST-GRADUATE TRAINING**

Transitional Internship, University of Hawaii, 1983-1984  
Residency, Internal Medicine, University of Hawaii, 1984-1986  
Fellowship, Diabetes and Clinical Nutrition, USC Medical Center, Los Angeles  
County, 1988-1990

#### **PROFESSIONAL EXPERIENCE**

##### **Current:**

1. Dept. of Endocrine, weight management, and nutritional disorders practice at Scripps Clinic, Del Mar, 1995 to present.
2. Director, Nutrition and Metabolic Research Center, Scripps Clinic, Del Mar, 1995 to present.

##### **Previous:**

1. Medical Director, Center for Weight Management at Scripps Memorial Hospital, La Jolla, CA, 1990-1995.
2. Medical Director, Nutrition Support Team, UCSD Medical Center, San Diego, CA, 1990-1995.
3. Private practice, clinical nutrition and metabolism, 1990-1995.
4. Editor, Clinical Nutrition Reviews, La Jolla, CA, 1990-1995.
5. Regional Director of a hospital-based weight loss program ("Weigh to Live"), Santa Monica Hospital, 1988 to 1990.
6. Locum Tenens in internal medicine, 1986 to 1990, (Hawaii, Colorado, and California).
7. Private practice, internal medicine, Vail, Colorado, 1986-1989.
8. Emergency room physician, Aspen Valley Hospital, 1987-1988.
9. Emergency room physician for spectrum of Hawaii, 1984-1987.

## RESEARCH

1. Snowboard Injuries. Fujioka K, Janes P, Sports Medicine Digest, Nov. 1989.
2. Effects of very low calorie diet on metabolic rate, serum chemistries, and plasma lipids. Fujioka K, Devine WS, and Gray DS, Poster at the annual ASCN meeting, Washington D.C., May, 1990. Abstract, Am J Clin Nutr 51:514, 1990.
3. Evaluation of a computerized nutrient analysis system in obese diabetics, Devine WS, Gray DS, Fujioka K, and Mack W, Abstract, Clinical Research 381, 1990.
4. Use of magnetic resonance imaging in determination of fat distribution in obesity and diabetes. Gray DS, Fujioka K, Colletti PM, Kim H, Devine WS, Cuyegkeng T, Am J Clin Nutr 51:514, 1990.
5. Use of relative weight and weight-height indices for the determination of adiposity. Gray DS, Fujioka K, J of Clinical Epidemiology, 44 (6):545-550, 1991.
6. Increased carbohydrate intake of National Basketball Association superstar athletes. Fujioka K, Kain D, Mackenzie RB, Gray DS, Dept. of Medicine, University of Southern California, Los Angeles, CA, Abstract, Am J Clin Nutr 53:18, 1991.
7. Abdominal obesity is associated with insulin resistance (determined by minimal model technique). Gray DS, Fujioka K, Devine WS, Cuyegkeng T, Buchanan T, abstract, International Journal of Obesity, 15(3):36, 1991.
8. Home care nutrition support team. Fujioka K, et al. Abstract and poster presented at the 16th ASPEN Clinical Congress (Orlando, Florida), January, 1992.
9. Optimizing nutrition support in patients with acute renal failure on CAVHD. Monson P, Fujioka K, Mehta RL. Abstract and poster presented at the 16th ASPEN Clinical Congress (Orlando, Florida), January 1992.
10. Silent gallstones in the obese female presenting to hospital-based weight loss programs. Abstract presented at NASSO meeting, September, 1992.
11. Fluoxetine treatment of the Obese Diabetic. Gray DS, Fujioka K, Devine WS, and Bray W. International Journal of Obesity 16:193-199, 1992.
12. Total parenteral nutrition in the AIDS patient with wasting syndrome. Fujioka K, Fujioka T, and Fredrick M. Journal of the American College of Nutrition, Abstract, 12(5):598, 1993.
13. Malnutrition is a common finding in the home care patient dependent on enteral therapy. Fujioka K, Schechter R, Wynne K. Journal of the American College of Nutrition, Abstract, 12(5):598, 1993.
14. Abdominal obesity is associated with insulin resistance. Gray DS, Fujioka K, Devine WS, Cuyegkeng T. Family Medicine 25(6):396-400, June 1993.
15. Medical management of obesity. Fujioka K. Hospital Medicine 32(11):28-35, 1996.
16. Characterization of serum leptin concentrations in the general population. The 950247 Leptin Study Group, Fujioka K, Staten M, et. al. Abstract and presentation at NAASO meeting, October, 1996.
17. Prevalence, characteristics and beliefs of physicians and the use of weight loss medications. Fujioka K, Blackstone RG, et. al. Abstract and poster presentation at NAASO meeting October, 1996.
18. Characteristics of the obese population treated by a specialist in an integrated health care system. Fujioka K, Yung S, et. al. Abstract and poster presentation at NAASO meeting, October, 1996.
19. Smaller Relative Nocturnal Rise of Serum Leptin Levels in Obese Patients. Lau DTW, Lubina J, Hseih A, Fujioka K, Heymsfield SB, Greenberg A, Kushner R, Staten M. Oral presentation NAASO annual meeting Nov. 1997.
20. Preliminary Safety and Efficacy of recombinant Methionyl Human Leptin(rL) Administration by SC Injection in Lean and Obese Subjects, Greenberg AS, Heymsfield SB, Fujioka K, Dixon R, Kushner R, Hunt T, Patane J, Self B, Staten M, McCamish M. Presented at the annual American Diabetes Assoc. annual meeting Chicago, 1998.
21. Sibutramine enhances weight loss in obese hypertensives patients taking angiotensin converting enzyme(ACE) inhibitors Fujioka K, Weinstein SP, Rowe E, McMahon FG Presented at the European Association of Diabetes annual meeting, Sept. 1998.
22. An Echocardiographic Scoring Algorithm for "Carcinoid-Like" Valvular Heart Disease in Patients Treated with Anorectic Drugs. Benson CT, Fujioka K, Rubenson DS. Abstract presented at the American College of Cardiology annual meeting, 1999.

23. Sibutramine : Weight Loss, Improved Lipids. Dujovne CA, Zavoral JH, Fujioka K, Alvaro AB, Goldberg AC, Alderman MH, Davidson MH, Stein EA, Mendel C, Rowe E. Abstract, Inter. J. Obesity 23;S176:1999.
24. Orlistat, a lipase inhibitor, for weight maintenance after conventional dieting: a 1-year study Hill JO, Hauptman J, Allison M, , Anderson JW, Fujioka K, , O'Neil PO, Perry A, Smith DK, Zavoral J, Aronne LJ. AJCN 69#6:1108-1116;1999.
25. Sibutramine enhances weight loss in obese hypertensive patients taking Calcium Channel Blockers. Fujioka K, Mooradian A, Mendel C, Rowe E. Abstract Inter. J. Obesity Vol. 23 S175:1999.
26. Recombinant leptin for weight loss in obese and lean adults: A randomized, controlled, dose-escalation trial, Heymsfield SB, Greenberg AS, Fujioka K, et. al. JAMA 282:1568-1575, 1999.
27. Relationship among DEXA and BIA Measures of Body Composition. Kushner R, Heymsfield S, Greenberg A, Fujioka K, et. al. . Presented at NAASO annual meeting November, 1999. Obesity Research 1):27, 1999.
28. Use of Sibutramine in a Managed care setting A Retrospective Study of Safety and Clinical Outcomes. Fujioka K, O'Connor JP, Nguyen MH, et. al. Presented at NAASO annual meeting November, 1999. Obesity Research 1):27, 1999.
29. CSF Leptin Levels after Exogenously administration of recombinant-human methionyl leptin (r-methHuLeptin) Fujioka K, Patane J, Lubina J, Lau D. Research Letter JAMA Vol. 282,#16 p15171518:199 Presented at NAASO annual meeting November, 1999.
30. Weight loss with Sibutramine improves glycemic control and other metabolic parameters in obese patients with type 2 diabetes mellitus. Fujioka K, Seaton TB, Rowe E, Jelinek CA, Raskin P, Lebovitz HE, Weinstein and the Sibutramine / Diabetes Clinical Study Group, Diabetes, Obesity, and Metabolism. #2, pp175-187: 2000.
31. Sibutramine-induced weight loss improves lipid profile in obese type 2 diabetics: Results of 3 placebo-controlled randomized trials. Rissanen A, Finer N, Fujioka K, Abstract American Diabetes Association Annual Meeting May 2000, Diabetes, 49; S1:A270.
32. Once-daily dosing of a meformin extended release (Met-XR) formulation: Effect on glycemic control in patients with type 2 diabetes currently treated with metformin. Fujioka K, Ledger SJ, Goyvaerts H, Jamoul C, Stein P, American Diabetes Association Annual Meeting May 2000, Diabetes 49;S1:A107.
33. Drug therapy for weight management. Fujioka K. Infertility and Reproductive Medicine Clinics of North America. 11:2, 2000.
34. Efficacy and safety of sibutramine in obese white and african american patients with hypertension. McMahon FG, Fujioka K, Singh BN, Mendel, CN, Rowe, E, Rolston K, Johnson F, Mooradian AD. Archives of Internal Medicine 160, 2000.
35. Significant body composition changes observed in obese subjects receiving chronic subcutaneous administration of a modified form of recombinant human leptin. Fujioka K, Murphy-Philkins R, Green D, De Paoli A, Le Bel C. Presented at NAASO annual meeting October, 2000. Obesity Research 8:1, 2000.
36. Potential dangers of dietary advice from the internet. Fujioka K, Picard F. Presented at NAASO annual meeting October, 2000. Obesity Research 8:1, 2000.
37. Sibutramine is safe and effective for weight loss in obese patient whose hypertension is well controlled with angiotensin-converting enzyme inhibitors. McMahon GF, Fujioka K. Journal of Human Hypertension in press
38. Bupropion SR significantly enhances weight loss when used with a Moderately-intensity lifestyle intervention. Anderson JW, Greenway F, Fujioka K, Gadde K, McKenny J, O'Neil P. In Press, Obesity Research
39. Health Care Utilization before and after Bariatric Surgery, the Managed Care Experience. K Fujioka, RH Toussi, ME Brunson, RA Mendes Oral presentation Obesity Research Vol.9S3: 2001
40. Management of Obesity as a Chronic Disease: Nonpharmacologic, Pharmacologic, and Surgical options K Fujioka. Obesity Research. Vol.10 Suppl.2 Dec. 2002
41. Glycemic control in patients with type 2 diabetes Mellitus switched from twice-daily immediate-release metformin to a Once-daily Extended-release formulation. K Fujioka, M Pans, S Joyal Clinical Therapeutics. Vol. 25, No.2 pp 515-529: 2003

42. Clinical Trials and anti-obesity agents, Editorial K Fujioka, Current Opinion in Investigational Drugs vol.4#10:1164-1165 Oct. 2003 p
43. Efficacy, dose-response relationship and safety of once-daily extended release metformin in type two diabetics. K Fujioka RL Brazg, I Raz, S Bruce, S Joyal, R Swanink, M Pans. Diabetes Obesity and Metabolism, 00, 1-12 2004 in press
44. The Effects of Grapefruit on Weight and insulin resistance: Relationship to metabolic syndrome K Fujioka, F Greenway, J Sheard. Diabetes vol 53 S2 A594 June 2004

#### **CLINICAL NUTRITION FELLOWSHIP**

The 2-year fellowship was a multi-disciplinary education which included:

1. Research Obesity and Nutrition.
2. Diabetes in-patients and out-patients
3. Rotations in the following areas:
 

A. Lipid Disorders	E. Endocrinology
B. Diabetes	F. Eating Disorders
C. Pediatric Nutrition	G. Athletic Nutrition
D. Gastroenterology	H. Obesity
4. Responsibility and supervision of the L.A. County General hospital nutrition support team which advised on all nutritional consults and nutritional complications.

#### **BOARD CERTIFICATIONS**

Internal Medicine, 1986  
Clinical Nutrition, 1990

#### **MEDICAL LICENSURE**

California (G059288)

#### **MEMBERSHIPS**

American Diabetes Association (ADA)  
North American Association for the Study of Obesity (NAASO)

#### **UNIVERSITY AFFILIATIONS**

University of California, San Diego - Assistant Clinical Professor

#### **HOSPITAL AFFILIATIONS**

Scripps Clinic Green Hospital - La Jolla, CA

#### **CLINICAL TRIAL EXPERIENCE**

- Over 75 clinical trials completed, the majority in metabolism related areas of obesity. Multiple studies in food intake in human beings and effects of food and food supplements. Other areas of experience are cholesterol, hypertension, diabetes, eating disorders.
- Approximately 25% of all studies are Principal Investigator initiated
- Experience in Phases 1-4.
- Consultant to several pharmaceutical companies and CROs to help in protocol design, review of obesity trials, and marketing.

#### **RECENT ABSTRACTS**

1. Reas, DL, Williamsons, DA, Greenway F, Raum, B, Fujioka K, Bethancourt I, Stewart L, Blanchard D, Arnett C, Walden H, Thaw J, Antolik E, Relationship between weight loss and body image in obese females seeking weight loss treatment. International J. of Obesity, 34(1), 12 : 2003
2. Fujioka K, Pirner M, Hewkin A, Renz C. Effects of Sibutramine-induced Weight loss on patients with metabolic syndrome. Abstract Obesity Research vol 11: pA110: 2003
3. Corby M, Greenway F, O'Neil P, Anderson J, Fujioka K, Gadde K, McKenney J, White M. The effect of Bupropion on food Craving over 24 weeks in a Multi-center weight loss trial. Abstract Obesity Research vol 11: pA110:2003



**INVITED LECTURES OVER THE PAST TWO YEARS**

Scripps Clinic Grand Rounds for the year 2002 and 2003  
Scripps Clinic Internal Medicine Grand Rounds  
Scripps Clinic general Grand Rounds  
Scripps Memorial Grand Rounds  
UCSD VA Endocrine Grand Rounds  
Joslin Clinic Diabetes Symposium  
UCLA Marin Luther King Hospital Endo Grand Rounds  
UCSF Psychiatric Grand Rounds  
Sharp Memorial (San Diego) Grand Rounds  
Grossmont Hospital (San Diego) Grand Rounds  
University of Hawaii Grand Rounds  
    Queens and St Francis Hospital  
University of Alberta Canada  
    Endocrine and Medicine Grand Rounds  
University of Calgary  
    Endocrine and Medicine Grand Rounds  
University of British Columbia  
    Endocrine and Medicine Grand Rounds  
University of Washington  
    Endocrine Grand Rounds

**GOVERNMENT PRESENTATIONS AND POSITIONS**

Invited Lecture to the Steering Committee for Public Policy of Congress on "Use and Abuse of Supplements," Washington DC  
Invited Lecture to the Medical Pharmacy Committee for the State of California, Sacramento  
Expert witness for the State of California on the appropriate use of weight treatments

**JOURNAL REVIEWER**

Journal of the American Medical Association (JAMA)  
Obesity Research  
Diabetes Care  
Obstetrics and Gynecology  
Diabetes Obesity and Metabolism

**EDUCATIONAL COMMITTEES**

North American Society for the Study of Obesity  
Scripps Clinic subspecialty and residency program, participating in the development of a comprehensive nutritional education program

**OVERSITE FOR RESIDENCY RESEARCH PROJECTS**

Abnormal LFTs in the Obese Population  
Computerized Web-Based Weight Loss Program  
Resistance Training vs. Aerobic Training for Weight Loss

## **EXHIBIT B**

1. Simpson, G. K. et al., Intermittent Protein-Sparing Fasting with Abdominal Belting, *International Journal of Obesity* (1986) 10, 247-254;
2. Garrow, J. S., The management of obesity. Another view, *International Journal of Obesity* (1992) 16 (Suppl. 2), S59-S63